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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/596,507	06/19/2000	Horst Peschel	4070-174US (K4004174US)	11/05/2002

570 7590 11/05/2002

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PHILADELPHIA, PA 19103

EXAMINER

HAYES, ROBERT CLINTON

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 11/05/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 09/596,507	Applicant(s) Peschel	
Examiner Robert C. Hayes, Ph.D.	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Aug 20, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 44-84 is/are pending in the application.
- 4a) Of the above, claim(s) 50 and 55-57 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 44-49, 51-54, and 58-84 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 44-84 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Response to Amendment

1. The amendment filed 8/20/02 has been entered.

2. Newly submitted claims 44-53, 55-57, 58-84 are directed to inventions that are independent or distinct from the invention originally claimed for the following reasons:

Claims 44, 55-57, 63, & 79 recite "partially-differentiated neuronal progenitor cells that... are capable of differentiating into substantially only a single type of neuron" unrelated to dopaminergic neurons, which alternatively represent their own distinct invention with different products and goals, and therefore, are restricted. It is noted that Applicants were previously informed that any such amendment of the claims, as it relates to this issue, would result in further restriction in Paper No: 9.

Claim 50 is also restricted because this represents different types of progenitor cells that are not derived from the central nervous system, and therefore, represents a different product.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 50, 55-57, as well as claims 44-53 & 58-84 as it relates to non-dopaminergic cells, are withdrawn from consideration as being directed to non-elected inventions. See 37 CFR 1.142(b) and MPEP § 821.03.

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This application contains claims 50, 55-57, as well as claims 44-53 & 58-84 as it relates to non-dopaminergic cells, drawn to an invention nonelected with traverse in Paper No. 7. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

3. Applicant's arguments filed 8/20/02 have been fully considered but they are not deemed to be persuasive.

4. Claim 52 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form, for the reasons made of record for cancelled claims 30 & 33 in Paper No:9.

5. Claims 44-49, 51-54 & 58-84 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons made of record for cancelled claims 26-43 in Paper No: 9 and as follows.

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No proper antecedent basis nor conception within context of that described within the specification exists for the current recitation of “synthetic neuronal tissue”, or for “partially differentiated neuronal progenitor cells that maintain their capability to preform mitosis” (versus the different concept of “dedifferentiation” discussed on page 5 of the specification; as it relates to claims 44, 63, 79), or for “differentiation-promoting factor are contacted for at least two hours” or “separated... after at least two hours” (i.e., as it relates to claims 80-81), or for “wherein the factor is an extracellular matrix of human tissue (i.e., as it relates to claims 62 & 65), or for “wherein the recipient and the mammal are the same individual” (i.e., as it relates to claim 82), or for “wherein the single progenitor cell is selected on the basis that it expresses a marker characteristic of the selected type of neuron” (i.e., as it relates to claim 83), or for “the single neuronal progenitor cell is proliferated by contacting the cell with a mitogen after selecting the cell”; thereby, constituting new matter. In contrast to Applicants’ assertions, no such proper basis exists on pages 1-9 of the specification.

No proper antecedent basis nor conception within context of that described within the specification exists for the recitation of “wherein the synthetic tissue does not comprise sufficient glial cells to provoke an immune response upon implantation of the synthetic tissue into a recipient” (versus the different concept of “not give rise to the immunogenic (*sic*) glial cells in large enough numbers” on page 2 of the specification; as it relates to claims 44, 63 & 79); thereby, constituting new matter.

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Additionally, as previously made of record, no proper antecedent basis nor conception within context of that described within the specification remains for the broader recitations of “>90/95% of cells in the synthetic tissue are the progenitor cells/partially-differentiated neuronal progenitor cells” (i.e., as it relates to claims 45-46 & 70), or for “partial differentiation is performed more than once” (i.e., as it relates to claim 71 versus the specific series of steps recited in original claim 11), or for the additional method steps recited in claim 63(f) or claims 79 & 83, etc., thereby, still constituting new matter.

6. Claims 44-49, 51-54 & 58-84 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons made of record for cancelled claims 26-43 and as follows.

It is noted that in contrast to various Applicant comments that include the comment that “the situation is not this simple”, the issue remains simply that neither the specification nor the claims state any closed-ended description that defines the metes and bounds for the following, or that the rejections previously made of record have not been accurately addressed.

The metes and bounds of what exactly constitute “synthetic neuronal tissue” (versus any other neuronal tissue), “differentiation factors” or “differentiating-promoting factors”, or how a “factor... [can be] an extracellular matrix of human tissue” that alternatively is tissue and not a

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“factor”, remains unknown. Note that the metes and bounds for what constitutes “factors” are addressed in claims 64 and 67-69.

It also remains unclear how, or why, glial cells derived from the same tissue as the “synthetic tissue” would have any different “immune response”. Either the “synthetic tissue” is rejected by the host, or it is not. It is noted that Applicants’ comments on page 11 of the response ignore this simply issue, in which currently unnecessary and confusing language remains in the claims.

7. Claims 44-49, 51-54 & 58-84 are rejected under 35 U.S.C. 102(b) as being anticipated by Boss et al. (US Patent 5,411,883; IDS Ref #3), for the reasons made of record for cancelled claims 26-43 in Paper No: 9:

8. Claims 44-49, 51-54 & 58-84 are rejected under 35 U.S.C. 102(b) as being anticipated by Emory University/Luskin et al. (WO 97/02049; IDS Ref #10), for the reasons made of record for cancelled claims 26-43 in Paper No: 9 and as follows.

In contrast to Applicants’ assertions on pages 13-15 of the response, the claims merely recite “capable of differentiating...”, which both Boss’ and Luskin’s neuronal progenitor cells, etc. reasonably possess, for the reasons previously made of record, and in which the term “synthetic tissue” provides, in itself, no distinguishable characteristics to obviate these rejections;

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especially when any tissue removed from an animal and manipulated reasonably meets the broad recitation of "synthetic neuronal tissue".

Accordingly, it has been established by the courts that a product inherently possesses characteristics of that product (i.e., including any inherent capabilities of neuronal progenitor cells). See, e.g., *Ex parte Gray*, 10 USPQ2d, 1922; *In re Best*, 195 USPQ 430). Additionally, "the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. Accordingly, since the issue in the present appeal is whether the prior art factor is identified or patently indistinct from that of the material on appeal, appellants have the burden of showing that inherency is not involved". *Ex parte Gray*, 10 USPQ 2d 1922 (1989); *In re Best*, 195 USPQ 430 (CCPA 1976).

Moreover, amendment of the claims to recite the product in a product-by-process claim does not obviate the rejections made of record, because when the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior art product was made by a different process. *In re Thorpe*., 227 USPQ 964, 966 (Fed. Cir. 1985); *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983).

Lastly, it is noted that the courts have held that when the prior art product reasonably appears to be the same as that claimed, but differs by process in which it is produced, a rejection of this nature is eminently fair and the burden is upon the appellants to prove, by comparative evidence, a patentable difference (*In re Brown*, 173 USPQ 685).

Therefore, Applicants' arguments are not persuasive.

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9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Robert C. Hayes, Ph.D.
October 21, 2002



GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600